IN THE MATTER OF

\* BEFORE THE

**NEB 24** 

STATE BOARD

d/b/a MARYLAND RESPIRATORY GROUP

OF PHARMACY

**PERMIT No: PW0305** 

Case No.: PI-10-017

**Respondent-Pharmacy** 

**CONSENT ORDER** 

On July 15, 2011, the State Board of Pharmacy (the "Board") charged **Maryland Respiratory Group d/b/a Neb 24 ("Respondent-Pharmacy"), Permit No.: PW0305,** the Maryland Pharmacy Act (the "Act"), Md. Health Occ. Code Ann. ("H.O.") §§ 12-101 *et seq.* (2009 Repl. Vol.).

Specifically, the Board charged the Respondent with the following provisions of the Act under H. O. § 14-404:

## H.O. § 12-403. Required Standards.

- (b) In general. Except as otherwise provided in this section, a pharmacy for which a pharmacy permit has been issued under this title:
- (1) Shall be operated in compliance with the law and with the rules and regulations of the Board;
- (2) Shall be located and equipped so that the pharmacy may be operated without endangering the public health or safety;
- (3) Shall ensure that a licensed pharmacist shall be immediately available on the premises to provide pharmacy services at all times the pharmacy is in operation; [and]
- (4) Shall be supervised by a licensed pharmacist who is responsible for the operations of the pharmacy at all times the pharmacy is in operation;

# H.O. § 12-409. Suspensions and revocations – Grounds.

(a) In general. – Subject to the hearing provisions of §12-411 of this subtitle, the Board may suspend or revoke any pharmacy permit, if the pharmacy:

- (2) Violates any of the standards specified in §12-403 of this subtitle[.] **COMAR 10.34.14.02 Information to be Included in Notification of Closing.** The notification after a pharmacy has been closed, referred to in Regulation .01, shall include the following information and documentation:
  - A. At least 14 days before a location's anticipated date of ceasing to operate as a licensed pharmacy, the pharmacy permit holder shall notify the Board in writing of the day on which the licensed pharmacy will cease to operate as a pharmacy. This notification shall be sent by certified mail, return receipt requested, or hand delivered to the Board's office.
  - B. Within 72 hours before or after ceasing to operate, the pharmacy permit holder shall request a closing inspection from the Division of Drug Control.
  - C. Upon notification by a pharmacy permit holder of the proposed date on which a licensed pharmacy will cease to operate, the Board shall notify the Division of Drug Control to schedule the closing inspection.
- **COMAR 10.34.14.03 Required Information and Procedure.** A. At the closing inspection of a licensed pharmacy, the pharmacy permit holder shall provide to the Division of Drug Control all information and documentation required by Regulation .04 of this chapter.
- **COMAR 10.34.14.04 Information and Documentation Due at the Closing Inspection.** The notification after a licensed pharmacy ceases to operate as a pharmacy, referred to in Regulation .03A of this chapter, shall include:
  - D. The names, address, telephone numbers, and Drug Enforcement Administration registration numbers of the persons or business entities to whom any prescription drugs in stock were returned or transferred under Regulation .05 of this chapter and for any prescription files or patient records transferred;

#### FINDINGS OF FACT

1. At all times relevant to the charges herein, the Respondent-Pharmacy was permitted to operate as a waiver pharmacy in the State of Maryland, having been issued permit number PW0305. The Respondent-Pharmacy was first issued a permit on April 11, 2007. The Respondent-Pharmacy's permit will expire on December 31, 2011.

- 2. At all times relevant, the Respondent-Pharmacy was owned by Al A. Balaa, RCP, Ph.D.
- 3. The Respondent-Pharmacy is currently located at 5711 Industry Lane, suite #33, Frederick, Maryland 21701.<sup>1</sup>
- 4. The Respondent-Pharmacy provides respiratory durable medical equipment and respiratory medications.
- 5. On December 8, 2009, the Board's inspector conducted an opening inspection for the Respondent-Pharmacy's relocation from 47 East All Saints Street to 5711 Industry Lane, suite #28. The facility met all of the requirements for opening. However, because there was no pharmacist on duty to be present for the inspection, Pharmacist A, who works at neighboring QD Pharmacy<sup>2</sup> ("QD"), located in Suite #32, had to come over to the Respondent-Pharmacy to witness the inspection.
- 6. On March 10, 2010, the Board's inspector conducted an annual inspection for the Respondent-Pharmacy. There was no pharmacist available, so Pharmacist B, who works at QD, had to come over to the Respondent-Pharmacy to witness the inspection.
- 7. On or about October 1, 2010, the Respondent-Pharmacy relocated to suite #33. The Respondent-Pharmacy failed to notify the Board to schedule a closing inspection (for suite #28) and an opening inspection (for suite #33) prior to its relocation.
- 8. On October 28, 2010, the Board's Inspector attempted to conduct an annual inspection of the Respondent-Pharmacy at suite #28. At that time, the Board's Inspector

<sup>&</sup>lt;sup>1</sup> Since becoming licensed by the Board, the Respondent-Pharmacy has relocated often, making it difficult to determine its correct address at any given time. Suite numbers 28, 33 and 30 are used interchangeably. <sup>2</sup> QD Pharmacy, which was under the same ownership as the Respondent-Pharmacy, closed as of March 31, 2011.

discovered that the Respondent-Pharmacy was no longer located in suite #28. The suite was empty and locked.

- 9. The Board's Inspector visited QD to inquire about the Respondent-Pharmacy and learned that it had moved to suite #33, which was adjacent to QD. The Respondent-Pharmacy and QD were sharing a space.
- 10. According to Ms. Fritz, who was present, no medications were moved from suite #28 to suite #33, as all of the medications were returned to the respective distributors. However, Ms. Fritz could not provide documentation in support of that claim.
- 11. On February 15, 2011, the Board's Inspector conducted an opening inspection for the Respondent-Pharmacy's new location in suite #33.
- 12. The Respondent-Pharmacy failed the opening inspection because it did not have running hot and cold water, and did not meet the security provisions set forth under COMAR 10.34.05.02A(2) and (5).
- 13. On April 7, 2011, the Board's Inspector attempted a second opening inspection for the Respondent-Pharmacy's new location in suite #33. The Respondent-Pharmacy again failed the opening inspection because there was no documentation of the medications that had allegedly been transferred from QD to the Respondent-Pharmacy. QD failed its closing inspection with the Division of Drug Control because it could not produce this documentation.
- 14. On April 14, 2011, the Board's Inspector attempted a third opening inspection for the Respondent-Pharmacy. The Respondent-Pharmacy failed the opening inspection again because it could not produce an alarm activity report.

15. On April 15, 2011, the Board's Inspector made a fourth attempt at an opening inspection for the Respondent-Pharmacy. At this time, the Respondent-Pharmacy passed the opening inspection.

16. The Respondent-Pharmacy's conduct as outlined above in pertinent part constitutes in whole or in part a violation of one or more of the following provisions under H.O. § 12-403(b)(1), (2), (3) and/or (4), and/or H.O. § 12-409(a)(2) and/or COMAR 10.34.14.02 and/or 10.34.14.03 and/or 10.34.14.04.

## **CONCLUSIONS OF LAW**

17. Based on the foregoing Findings of Fact, the Board concludes as a matter of law that the Respondent violated the following provision of the Act: under H.O. § 12-403(b)(1), (2), (3) and/or (4), and/or H.O. § 12-409(a)(2) and/or COMAR 10.34.14.02 and/or 10.34.14.03 and/or 10.34.14.04.

#### ORDER

Based on agreement of the parties, it is therefore this day of September 2011, by an affirmative vote of the Board, hereby:

**ORDERED** that the Respondent-Pharmacy shall pay a fine in the amount of \$1,000, payable to the Maryland Board of Pharmacy, within thirty (30) days of the date of this Order; and it is further

ORDERED that the Respondent-Pharmacy shall bear all expenses associated with this Order; and it is further ORDERED that the Respondent-Pharmacy shall operate according to the Maryland Pharmacy Act and in accordance with all applicable laws, statutes and regulations pertaining to the practice of pharmacy; and it is further

ORDERED that this document constitutes a formal disciplinary action of the State Board of Pharmacy and is therefore a public document for purposes of public disclosure, pursuant to the Public Information Act, State Gov't § 10-611 et seq. and COMAR 10.34.01.12.

Michael N. Souranis, P.D., President

## **CONSENT**

I, Al A. Balaa, RCP, Ph.D, owner and operator of Neb24, acknowledge that I opted not to consult with legal counsel before signing this document. By this Consent, I accept to be bound by this Consent Order and its conditions and restrictions. I waive any rights I may have had to contest the Findings of Fact and Conclusions of Law.

I acknowledge the validity of this Consent Order as if entered into after the conclusion of a formal evidentiary hearing in which I would have had the right to counsel, to confront witnesses, to give testimony, to call witnesses on my own behalf, and to all other substantive and procedural protections as provided by law. I acknowledge the legal authority and the jurisdiction of the Board to initiate these proceedings and to issue and enforce this Consent Order. I also affirm that I am waiving my right to appeal any adverse ruling of the Board that might have followed any such hearing.

I sign this Consent Order without reservation, and I fully understand and comprehend the language, meaning and terms of this Consent Order. I voluntarily sign this

Date

Al A. Balaa, RCP, Ph.D., owner and operator Neb24, Respondent-Pharmacy

NOTARY
STATE OF MARYLAND
CITY/COUNTY OF Baltimore:
I HEREBY CERTIFY that on this 15 day of November, 2011, before
me, a Notary Public of the foregoing State personally appeared Al A. Balaa, RCP, Ph.D.,
owner and operator of Neb24, Permit Number PW0305, and made oath in due form of law
that signing the foregoing Consent Order was his voluntary act and deed, and the
statements made herein are true and correct.

AS WITNESSETH my hand and notarial seal.

Order, and understand its meaning and effect.

**Notary Public** 

My Commission Expires: 9/7/2014

CORJUAN C COOPER

NOTARY PUBLIC
BALTIMORE COUNTY
MARYLAND
Y COMMISSION EXPIRES SEPT. 7, 2014